UNITED STATES DISTRICT COURT
DISTRICT OF NEW HAMPSHIRE

Karen L. Bartlett

v.

Civil No. 08-cv-00358-JL
Opinion No. 2010 DNH 164

Mutual Pharmaceutical Company, Inc.

MEMORANDUM ORDER

This products liability case arises out of severe injuries that plaintiff Karen Bartlett suffered after ingesting sulindac, a prescription drug manufactured by the defendant, Mutual Pharmaceutical Company. Bartlett brought claims against Mutual for strict liability, negligence, and fraud under New Hampshire common law. Her principal theories were that sulindac is a defective product unreasonably dangerous to consumers and that Mutual failed to warn of the drug's safety risks. This court, which has jurisdiction under 28 U.S.C. § 1332(a)(1) (diversity), granted summary judgment to Mutual on Bartlett's strict liability and negligence claims to the extent they were based on failure to warn, and also on her fraud claim, because she could not prove that sulindac's allegedly inadequate warning caused her injuries. See Bartlett v. Mut. Pharm. Co., 2010 DNH 112. Bartlett proceeded to trial and prevailed on her strict liability claim of defective design.

After the summary judgment ruling, but in advance of trial, this court ordered the parties to brief whether Bartlett had sufficient evidence to support her negligence claim (under some theory other than failure to warn) and, if not, whether she could still pursue enhanced compensatory damages in connection with her strict liability claim. Bartlett responded by submitting her evidence in support of three negligence theories: that Mutual failed to (1) seek Food & Drug Administration ("FDA") approval of a patient medication guide for sulindac; (2) survey the medical literature for information about sulindac's safety risks and report such information to the FDA; and (3) file a citizen's petition with the FDA regarding sulindac's safety risks. She further argued that, even if this court rejected those negligence theories, the jury could award enhanced compensatory damages on her strict liability claim.

Having reviewed Bartlett's submission and Mutual's corresponding brief, this court concludes that Bartlett's negligence claim is mostly a self-described attempt to "resurrect" her failure-to-warn theories, in contravention of this court's summary judgment ruling. See Bartlett, 2010 DNH 112, at 11-22. To the extent that the negligence claim is based on conduct other than Mutual's alleged failure to warn, Bartlett has not presented sufficient evidence to prove that conduct caused her injuries. And since her claim for enhanced

compensatory damages is based on that same conduct, it also fails for lack of causation, regardless of whether a strict liability claim can theoretically sustain such damages. Mutual is therefore granted judgment as a matter of law on Bartlett's claims for negligence and enhanced compensatory damages. See Fed. R. Civ. P. 56.

The court initially announced this ruling in a summary order issued before trial. See document no. 329. This order sets forth the court's reasoning in greater detail.

I. Applicable legal standard

"It is without question that district courts, in appropriate circumstances, are entitled to enter summary judgment sua sponte." P.R. Elec. Power Auth. v. Action Refund, 515 F.3d 57, 64 (1st Cir. 2008). To guard against any unfairness to the parties, our court of appeals has "required two conditions prior to the district court's exercise of such a right:" (1) "the discovery process must be sufficiently advanced that the parties have enjoyed a reasonable opportunity to glean the material facts," and (2) "the district court must provide the targeted party appropriate notice and a chance to present its evidence on the essential elements of the claim." Id. at 64-65.
Both of those conditions have been met here: the discovery

process is over, and this court gave Bartlett notice and an opportunity to present evidence on her claims for negligence and enhanced compensatory damages.[1] This court will therefore evaluate those claims as it would in the context of a summary judgment motion filed by Mutual.

Summary judgment is appropriate where "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c)(2). An issue is "genuine" if it could reasonably be resolved in either party's favor at trial, and "material" if it could sway the outcome under applicable law. Mulvihill v. Top-Flite Golf Co., 335 F.3d 15, 19 (1st Cir. 2003). In making that determination, the "court must scrutinize the record in the light most flattering to the party opposing the motion, indulging all reasonable inferences in that party's favor." Id. The following factual summary is consistent with that approach.

[1]See documents no. 281 (order), 305 to 318 (Bartlett's brief and supporting exhibits), and 303 (Mutual's brief). In addition to the briefing, this court discussed its concerns about Bartlett's negligence claim with the parties during the final pre-trial conference. See document no. 301.

II. Background

In December 2004, Bartlett sought medical treatment for pain in her right shoulder. Her doctor, Tahsin Ergin, prescribed a non-steroidal anti-inflammatory drug ("NSAID") called Clinoril, which the FDA has approved as a treatment for acute shoulder pain. Dr. Ergin did not read the potential adverse reactions and safety warnings listed in the drug's label (or "package insert"), but he knew from his medical background that sulindac and other NSAIDs carried some risk of causing potentially fatal skin conditions called Stevens-Johnson Syndrome ("SJS") and toxic epidermal necrolysis ("TEN"). See Dorland's Illustrated Medical Dictionary 1872 (31st ed. 2007). It was not his usual practice to discuss that risk with patients, and he did not do so with Bartlett.

Bartlett took the prescription to a pharmacy in Plaistow, New Hampshire, which filled it with sulindac, a generic version of the drug, manufactured by Mutual. The pharmacy gave Bartlett a "prescription advisor," which she read, that advised her to "check with your doctor as soon as possible if you experience rash or other skin conditions." Within weeks, Bartlett went to a local emergency room complaining of skin blisters, a fever, eye irritation, and other symptoms. She was soon diagnosed with a severe case of SJS/TEN. The consensus among her doctors was that her SJS/TEN was a side effect of sulindac. She spent about three

months in the hospital recovering, two of them in a medically induced coma, and emerged with permanent injuries, including blindness.

More than a year before Bartlett's prescription, an international medical journal published a study of the link between NSAIDs and SJS/TEN. See Maja Mockenhaupt et al., The Risk of SJS and TEN Associated with NSAIDs: A Multinational Perspective, 30 Journal of Rheumatology 2234-2240 (Oct. 2003). The article revealed that, from 1980 to 1997, the FDA's adverse event reporting system received 89 reports of SJS/TEN attributed to sulindac, more than the number of reports for any other NSAID on the market and all but four drugs of any kind. The article also noted that sulindac was one of four NSAIDs whose rate of reported SJS/TEN cases, per one million prescriptions, was not significantly lower than that of piroxicam, which the authors chose as the "comparator drug" because of its "high risk" in a controlled study.[2]

[2]Unpublished drafts of the article, prepared privately for the drug manufacturer Pharmacia by Dr. Robert Stern (who was later retained as an expert witness by Mutual) in 2001 and 2002, listed the precise reporting rates of SJS/TEN for various NSAIDs. Sulindac's rate was higher than that of any other NSAID listed. See documents no. 307-1 and 308-1.

Mutual was not aware of that Journal of Rheumatology article or adverse event reporting data, because (by its own admission) it had not been monitoring the medical literature for information about sulindac's safety risks. See document no. 149, at 15. Mutual believed that the manufacturer of Clinoril, the brand-name version of the drug, was responsible for such monitoring and for reporting pertinent safety information to the FDA. Id. at 16, 22-23; but see Bartlett, 2010 DNH 112, at 30-32 (concluding that generic drug manufacturers are also responsible for safety surveillance and reporting under 21 C.F.R. § 314.80(b)).

While Bartlett was in the hospital battling SJS/TEN, a group of doctors (including two whom Bartlett later retained as expert witnesses) filed a citizen's petition with the FDA advocating a stronger SJS/TEN warning in the label for another NSAID, ibuprofen. Soon thereafter, the FDA required not just ibuprofen, but all NSAIDs, including sulindac, to insert a stronger SJS/TEN warning in their labels. See Bartlett, 2010 DNH 112, at 15 n.6 (setting forth the language of that new warning). The FDA also required that all NSAIDs be accompanied by a patient medication guide, see 21 C.F.R. § 208.1, with an express warning of "life-threatening skin reactions" and an instruction that patients should stop taking the drug if they experienced "skin rash or blisters with fever."

In a written response to the citizen's petition, the FDA explained that it had "engaged in a comprehensive review of the risks and benefits, including the risks of SJS/TEN, of all approved NSAID products," and that it had specifically reviewed the Journal of Rheumatology article and the adverse event reporting data referenced above. Based on that review, the FDA concluded that one NSAID, Bextra, should be withdrawn from the market due to its SJS/TEN and cardiovascular ("CV") risks. The FDA explained:

> We have concluded . . . that Bextra has been demonstrated to be associated with an increased risk of serious adverse CV events . . . . The increased risk of serious adverse CV events alone, however, would not be sufficient to warrant withdrawal of Bextra since we have no data showing that Bextra is worse than other NSAIDs with regard to CV risk. Our recommendation for withdrawal is based on the fact that, in addition to this CV risk, [Bextra] already carries a boxed warning in the package insert for serious, and potentially life-threatening, skin reactions (e.g., TEN, SJS, erythema multiforme) and FDA has received 7 spontaneous reports of deaths from these reactions. The reporting rate for these serious skin reactions appears to be greater for Bextra than other [NSAIDs called] COX-2 selective agents . . . . To date, there have been no studies that demonstrate an advantage of [Bextra] over other NSAIDs that might offset the concern about these serious skin risks.

Bextra was the fourth drug to be removed from the market due, in part, to its SJS/TEN risk as demonstrated by adverse event reports.[3]

[3]The others were benaxaprofen, zomepirac acid, and isoxicam. Since then, the FDA has also refused to approve the drug Provigil for pediatric use because of its SJS/TEN risk.

Although sulindac had more reported cases of SJS/TEN than any other NSAID and more reported deaths (39) than Bextra, the FDA did not recommend that sulindac be removed from the market after its "comprehensive review" of all NSAIDs in 2005. In fact, sulindac remains on the market to this day. Mutual has never filed a citizen's petition with the FDA regarding the safety of sulindac or seeking its removal from the market. The company has, however, filed nine citizen's petitions for other reasons between 2001 and 2009, including one petition regarding the dosage form of sulindac and various petitions regarding safety information in the labels of other drugs (some manufactured by Mutual's competitors). The FDA has generally responded to those petitions in less than a year.

III. Analysis

As explained above, this court ordered the parties before trial to brief (A) whether Bartlett had sufficient evidence to support her negligence claim, and (B) if not, whether she could still pursue enhanced compensatory damages in connection with her strict liability claim. As explained below, the answer to both questions is no. Mutual is therefore granted judgment as a matter of law on Bartlett's claims for negligence and enhanced compensatory damages.

A. *Negligence claim*

Bartlett has submitted evidence in support of three negligence theories: that Mutual (1) failed to seek FDA approval of a medication guide for sulindac; (2) failed to survey the medical literature for information about sulindac's safety risks and to report such information to the FDA; and (3) failed to file a citizen's petition with the FDA seeking either sulindac's removal from the market or the removal of its approved indication for acute shoulder pain. Bartlett claims that "the duty that was breached [by Mutual] in each of these areas is the failure to communicate with the FDA as a reasonable manufacturer would have."[4]

To prevail on any of those theories, Bartlett must prove that Mutual's negligent conduct caused her injuries. See Carignan v. N.H. Int'l Speedway, Inc., 151 N.H. 409, 414 (2004). Causation has two components: the plaintiff must show, first, "that the injury would not have occurred but for the negligent conduct," and second, "that the negligent conduct was a substantial factor in bringing about the harm." Id. Here, Bartlett claims that if Mutual had taken any of steps listed

[4]Bartlett expressly withdrew her claim for negligent design, see document no. 301, at 15, and implicitly withdrew or waived any other negligence theories by not raising them in her submission, see document no. 305.

above, the FDA would have (1) required a patient medication guide for sulindac before her prescription, rather than after it, (2) removed sulindac's approved indication for acute shoulder pain, and/or (3) removed sulindac from the market, any of which would have prevented her from taking the drug and thus prevented her injuries.

This court will address each of Bartlett's negligence theories in turn. As explained below, most of them are really failure-to-warn theories and are therefore barred by this court's summary judgment ruling, which granted summary judgment to Mutual on all such theories. See Bartlett, 2010 DNH 112, at 11-22. The only one that is not a failure-to-warn theory is Bartlett's claim that the FDA would have removed Sulindac from the market if Mutual had advocated that removal in a citizen's petition or had submitted the latest safety information from the medical literature. But that claim fails because its causal chain depends on improbable inferences and speculation. See Enica v. Principi, 544 F.3d 328, 336 (1st Cir. 2008) ("summary judgment cannot be defeated by relying on improbable inferences, conclusory allegations, or rank speculation").

i. Patient medication guide

Bartlett's first negligence theory is that Mutual should have sought FDA approval of a patient medication guide for sulindac. The FDA may require that a drug be accompanied by a medication guide if it determines that "patient labeling could help prevent serious adverse effects," that safety information "could affect patients' decision to use, or to continue to use" the drug in the face of "serious risk(s)," or that "patient adherence to directions for use is crucial to the drug's effectiveness." 21 C.F.R. § 208.1. As discussed above, the FDA required a medication guide for sulindac and all other NSAIDs not long after Bartlett's prescription. Bartlett argues that the FDA would have required a medication guide before her prescription if Mutual had sought it, and that she never would have ingested sulindac if she had read the guide.

This court expressly rejected Bartlett's medication guide theory (among other failure-to-warn theories) in its summary judgment ruling, both because Bartlett failed to raise it in her summary judgment objection and because, on the merits,

> it is well established [under New Hampshire law] that a manufacturer's duty to warn of a drug's safety risks "requires that the physician, not the patient, be warned." Brochu v. Ortho Pharm. Corp., 642 F.2d 652, 661 (1st Cir. 1981); see also Nelson v. Dalkon Shield Claimants Trust, No. 84-276-SD, 1994 WL 255392, at *4 (D.N.H. June 8, 1994). Since Mutual had no duty to warn Bartlett directly, its failure to issue such a warning (in the form of a medication guide or

> otherwise) cannot serve as the basis for a finding of causation.

Bartlett, 2010 DNH 112, at 20. The principle articulated in that passage is known as the "learned intermediary" rule, because its underlying rationale "is that the prescribing physician, as the 'learned intermediary' standing between the manufacturer and the consumer/patient, is generally in the best position to evaluate the [drug's] potential risks and benefits . . . and to advise the patient accordingly." Nelson, 1994 WL 255392, at *4 (quoting Garside v. Osco Drug, Inc., 976 F.2d 77, 80 (1st Cir. 1992)).

Bartlett's self-described attempt to "resurrect" her medication guide theory in the face of that express summary judgment ruling is really a motion for reconsideration. See Rodriquez-Antuna v. Chase Manhattan Bank Corp., 871 F.2d 1, 2 (1st Cir. 1989) ("a motion which asks the court to modify its earlier disposition . . . solely because of an ostensibly erroneous legal result" is a motion for reconsideration). This court will analyze it as such. A motion for reconsideration must "demonstrate that the order was based on a manifest error of fact or law" and must be filed within 14 days of the order, unless the party shows cause for not filing it within that time. L.R. 7.2(e). Here, Bartlett sought reconsideration about a month

after the court's ruling, well after the 14-day deadline.[5] She has not shown good cause for that delay. Her request is therefore denied as untimely.

Even if it were timely, however, Bartlett's request for reconsideration would still be denied, because she has not identified a "manifest error of fact or law" in this court's ruling. She makes three arguments in that regard:

First, Bartlett argues that this court should not have considered her medication guide theory at all because it was "not raised" by Mutual's summary judgment motion, which in her view "missed the boat" by focusing solely on the drug's label. But this argument sinks. Mutual moved for summary judgment on all of Bartlett's claims, including her negligence claim, arguing that "failure to warn is the common thread in each alleged liability theory." Thus, Bartlett had the burden to come forward with evidence to support all of her failure-to-warn claims, including her medication guide theory and any other "non-label" theories. See Evans Cabinet Corp. v. Kitchen Int'l, Inc., 593 F.3d 135, 140 (1st Cir. 2010). Instead, she focused on her label-based theories. A motion for reconsideration "does not provide a

[5]By that point, Mutual had filed not only a motion for reconsideration of the summary judgment ruling, see document no. 263, but a motion for reconsideration of the court's denial of its first motion for reconsideration, see document no. 293.

vehicle for a party to undo its own procedural failures." Iverson v. City of Boston, 452 F.3d 94, 104 (1st Cir. 2006).[6]

Second, Bartlett argues that this court should create a special exception to the learned intermediary rule for medication guides, since they are a "new development" in the law, see 21 C.F.R. § 208.1, having been introduced by the FDA in 1998, four years after the most recent case that applied the learned intermediary rule under New Hampshire law. See Nelson, 1994 WL 255392, at *4. In her summary judgment objection, though, Bartlett called it "an uncontested claim [that] the learned intermediary doctrine means the drug company need only adequately warn the physician." She did not argue for a special exception for medication guides. A motion for reconsideration "does not . . . allow a party to advance arguments that could and should have been presented" earlier. Iverson, 452 F.3d at 104.

Moreover, even if Bartlett's argument had been properly presented, this court is not persuaded that medication guides constitute so significant a change to prescription drug labeling as to warrant what would amount to a significant change to (and

[6]During oral argument on the summary judgment motion, this court asked Bartlett about her "non-label" theories in an abundance of caution, i.e., to determine if they might somehow salvage her failure-to-warn claims, not (as Bartlett seems to believe) in an attempt to expand its summary judgment ruling beyond the scope of Mutual's motion. Those theories would be barred now even if this court had never mentioned them.

expansion of) state tort law. Indeed, the FDA expressed precisely the opposite view when it promulgated the medication guide regulation, stating that "FDA does not believe that this rule would adversely affect civil tort liability" because it "does not alter the duty, or set the standard of care for manufacturers," and because "courts have not recognized an exception to the 'learned intermediary' defense in [other] situations where FDA has required patient labeling." 63 Fed. Reg. 66378, 66383-66384 (Dec. 1, 1998).

Bartlett has not identified, nor has this court found, any case that supports her view that medication guides warrant a special exception to the learned intermediary rule, which remains "nearly universal." 5 Louis R. Frumer & Melvin I. Friedman, Products Liability § 50.04[2], at 50-58.1 (2010). "A federal court sitting in diversity cannot be expected to create new doctrines expanding state law," Noonan v. Staples, Inc., 556 F.3d 20, 27-28 (1st Cir. 2009), and this court declines Bartlett's invitation to do so here.

Third, Bartlett argues that a medication guide, because it is "reprinted at the end of the [drug's] labeling" or package insert, 21 C.F.R. 201.57(f)(2), can be considered a warning to doctors (not just patients) and thus is not barred by the learned intermediary rule. As explained in this court's summary judgment ruling, however, Bartlett's doctor did not read or rely upon

sulindac's label before prescribing the drug to her. So the medication guide, even if reprinted there, would not have affected the doctor's decision or prevented Bartlett's injuries. Thus, Mutual's failure to seek a medication guide cannot be considered the cause of Bartlett's injuries. See Carignan, 151 N.H. at 414.[7]

ii. Removal of indication for shoulder pain

Bartlett's second negligence theory is that, if Mutual had filed a citizen's petition with the FDA or otherwise submitted

[7]While on the topic of medication guides, it is worth taking a moment to explain the evidentiary rulings on that topic. This court initially granted Mutual's motion in limine seeking to exclude from trial any evidence regarding medication guides, "because they would imply a duty to warn the patient, would be confusing to the jury and unfairly prejudicial to Mutual." Bartlett v. Mut. Pharm. Co., 2010 DNH 131, at 19 (citing Fed. R. Evid. 403). At trial, however, this court orally modified that ruling, allowing evidence of the medication guide to be admitted with a cautionary instruction designed to avoid juror confusion and unfair prejudice. The cautionary instruction was given several times during the trial, including in the final jury charge. See document no. 378, at 21-22.

The reasons for that modification were twofold. First, since the jury was allowed to consider the changes that the FDA made to sulindac's labeling in 2005, see Bartlett, 2010 DNH 131, at 4-7, and the medication guide was part of those changes, it was necessary to give the jury a complete and accurate understanding of what the FDA did. Second, this court determined that the jury could consider the medication guide in evaluating "the presence and efficacy of a warning to avoid an unreasonable risk of harm," which is an analytically distinct question from whether Mutual had a duty to warn via a medication guide. Bartlett v. Mut. Pharm. Co., No. 08-cv-358, 2010 WL 3303864, at *1 (D.N.H. Aug. 16, 2010) (document no. 345) (quoting Vautour v. Body Masters Sports Indus., Inc., 147 N.H. 150, 154 (2001)).

information from the medical literature regarding sulindac's risk of SJS/TEN, the FDA would have removed sulindac's approved indication for acute shoulder pain, "advising doctors of this through effective means" and thereby preventing Bartlett's doctor from prescribing the drug to her for that purpose. As Bartlett's reference to "advising doctors" betrays, however, this too is really a failure-to-warn theory, which Bartlett could have and should have raised in her summary judgment objection. Since she failed to do so, the theory has been waived. See Iverson, 452 F.3d at 104 (a motion for reconsideration "does not . . . allow a party to advance arguments that could and should have been presented" earlier).

Moreover, even if Bartlett's removal-of-indication theory had been properly presented, this court would have rejected it on the merits. A prescription drug's approved indications, like its potential adverse reactions and warnings, are set forth in its label. See 21 C.F.R. § 201.57(c). As explained in this court's summary judgment ruling, Bartlett's doctor did not read or rely upon sulindac's label before prescribing the drug to her. So the deletion from that label of the indication for acute shoulder pain would not have affected the doctor's decision or prevented Bartlett's injuries. Thus, Mutual's failure to seek a removal of the indication cannot be considered the cause of Bartlett's injuries. See Carignan, 151 N.H. at 414.

Seemingly unfazed by the rules of summary judgment, Bartlett also argues that her doctor might have learned of the removal-of-indication (or other label changes) from an FDA press release, public health advisory, or mass mailing to physicians. This court expressly rejected that argument in its summary judgment order, explaining that it had been "untimely and improperly raised" in Bartlett's separate limine briefing, not in her summary judgment objection (or even at oral argument on the summary judgment motion), and was therefore waived. See Bartlett, 2010 DNH 112, at 19 n.9. The argument has not become any more timely or proper in the intervening period.[8]

iii. Removal from the market

Bartlett's third negligence theory is that if Mutual had filed a citizen's petition with the FDA or otherwise submitted information from the medical literature regarding sulindac's risk of SJS/TEN (including the Journal of Rheumatology article, which revealed that sulindac had more reported cases of SJS/TEN in the FDA's adverse event database than any other NSAID), the FDA would have removed sulindac from the market entirely, thus preventing

[8]Moreover, Bartlett still has not presented any evidence that her doctor would have read any such materials--only his deposition testimony (unmentioned in her summary judgment and limine briefing) that "as physicians we'll often receive them." Of course, receiving a mass mailing is not the same as reading it.

Bartlett's doctor from prescribing it and thereby preventing her injuries. This is Bartlett's only negligence theory that is not based on failure to warn and hence is not barred by this court's summary judgment ruling. Nevertheless, the theory suffers from a number of other fatal flaws.

The theory's most obvious flaw, which this court discussed briefly in a previous order, is that it is "contrary to what has actually happened." Bartlett, 2010 DNH 131, at 11. The FDA said that it "engaged in a comprehensive review of the risk and benefits, including the risks of SJS/TEN, of all approved NSAID products" in 2005, after receiving a citizen's petition from a group of doctors (two of whom later became Bartlett's experts). As part of that review, the FDA specifically considered the Journal of Rheumatology article and the adverse event reporting data. While deciding to strengthen the SJS/TEN warning on all NSAID labels, the FDA concluded that only one NSAID should be removed from the market due in part to its SJS/TEN risk: Bextra. "Sulindac remains on the market today . . . even though the FDA has long been aware of the adverse event data and medical literature upon which Bartlett relies." Id. at 11-12.

Bartlett argues that sulindac's risk-benefit profile was actually even worse than Bextra's. Regardless of how the two drugs compare, however, the bottom line is that the FDA concluded that Bextra should be removed from the market, but that sulindac

could stay on the market with a stronger SJS/TEN warning. Bartlett's theory that the FDA would have removed sulindac from the market if Mutual had submitted the Journal of Rheumatology article and other available information from the medical literature is counterfactual. Cf. Buckman Co. v. Pls.' Legal Comm., 531 U.S. 341, 353 (2001) (Stevens, J., concurring in the judgment, joined by Thomas, J.) ("The fact that the FDA has done nothing to remove the devices from the market, even though it is aware of the basis for the [plaintiff's] fraud allegations, convinces me that [causation] cannot be proved.").

Bartlett attempts to overcome this problem by pointing to earlier, unpublished drafts of the Journal of Rheumatology article (prepared by defense expert Dr. Stern for the drug manufacturer Pharmacia in 2001 and 2002), which contain additional information about sulindac's SJS/TEN risk that did not appear in the final article. Specifically, the drafts reveal that sulindac's rate of reported SJS/TEN cases per million prescriptions (not just its absolute number of reports) was the highest of any NSAID listed. Bartlett argues that Mutual should have obtained those unpublished drafts and submitted them to the FDA, which (she claims) has never considered that reporting rate data and would have responded by recommending sulindac's removal from the market.

There is insufficient evidence, though, to support any of the links in that causal chain. Even assuming, dubitante, that a reasonable manufacturer would have asked the authors of a published, peer-reviewed article for their unpublished drafts (a proposition for which Bartlett has not offered any expert testimony or other evidence), there is no evidence from which a jury could reasonably conclude that such a request would have been granted. Dr. Stern testified that, because of his contract with Pharmacia, he had to seek Pharmacia's permission even to use the unpublished data in developing the Journal of Rheumatology article. Pharmacia granted his request, but the current record provides no basis for reliably evaluating whether it would have allowed the unpublished drafts to be shared directly with a competitor like Mutual, leaving this link in the causal chain to speculation.

There is likewise no evidence from which a jury could reasonably conclude that Pharmacia did not itself share those unpublished drafts with the FDA. While Dr. Stern did not send the drafts to the FDA himself and has no "direct knowledge" of whether Pharmacia did so, he considers it a "high likelihood that Pharmacia would have filed a report of this type" with the FDA. Of course, Dr. Stern's speculation is not dispositive. But without any evidence of what Pharmacia actually did, it would be equally speculative to conclude that the FDA never received the

drafts. See Enica, 544 F.3d at 336 ("summary judgment cannot be defeated by relying on improbable inferences, conclusory allegations, or rank speculation").

Moreover, even if Pharmacia never shared Dr. Stern's reporting rate calculations with the FDA, those calculations were based entirely on publicly available information from the federal government. Dr. Stern used, as his numerator, the number of SJS/TEN reports for each drug in the FDA's own adverse event reporting database. And he used, as his denominator, the estimated number of prescriptions for each drug in the National Ambulatory Medical Care Survey ("NAMCS"), compiled by the federal Centers for Disease Control and Prevention ("CDC"). The FDA's analyses of Bextra in 2005 and Provigil in 2007 both indicate that, either through those government sources or other means, the FDA has the ability to calculate and has calculated the SJS/TEN reporting rates for NSAIDs.[9]

Finally, even assuming, dubitante, that the FDA was unaware of the precise SJS/TEN reporting rates for sulindac and other

[9] See document no. 309-1, at 12 ("While other COX-2 selective and non-selective NSAIDs also have a risk for these rare, serious skin reactions, the reported rate for these serious side effects appears to be greater for Bextra than for other COX-2 agents."); id. at 17 ("The reporting rate for these serious skin reactions appears to be greater for Bextra than other COX-2 selective agents."); document no. 309-3, at 19 ("the calculated reporting rate for [Provigil] associated SJS/TEN in all ages in the U.S. is 5.7 per 1,000,000 patients as compared to the background rate of 1-2").

NSAIDs, the final article published in the Journal of Rheumatology (which the FDA definitely did review) expressly listed sulindac as one of only four NSAIDs with a reporting rate comparable to that of piroxicam, which the authors chose as the "comparator drug" because of its "high risk" in a controlled study. The clear implication was that sulindac had one of the highest SJS/TEN reporting rates among NSAIDs (albeit without reference to the precise numbers). Despite that information, the FDA did not conclude that sulindac should be removed from the market. Bartlett's claim that more specific data would have changed the FDA's mind is, again, pure speculation. See Enica, 544 F.3d at 336.

This court recognizes that it is not possible to prove with absolute certainty what the FDA would have done in response to hypothetical communications that never occurred. To the extent, if any, that failure to communicate with the FDA can serve as a basis for a state negligence claim, see infra (discussing federal pre-emption concerns raised by such claims under Buckman, 531 U.S. at 341), the plaintiff must be given some inferential leeway in establishing causation. See, e.g., Stanton v. Astra Pharm. Prods., Inc., 718 F.2d 553, 568 (3d Cir. 1983) (holding, albeit before Buckman, that a reasonable jury could find causation based on "evidence tending to show that the information withheld from the FDA was of great importance . . . and that the FDA would have

taken action had it been aware of [the drug's] propensity to cause adverse reactions"). But the inferences still must be reasonable, not improbable or based "upon speculation as to the FDA's behavior in a counterfactual situation," which is the case with Bartlett's negligence theory. Buckman, 531 U.S. at 354 (Stevens, J., concurring in the judgment).

Bartlett also seems to be suggesting the FDA would have taken a harder look at sulindac and ultimately reached a different decision if Mutual, one of the drug's own manufacturers, had filed a citizen's petition requesting its removal from the market. But that too is speculative, at least on the record before the court. There is no evidence to suggest that the FDA makes its decisions that way. The FDA claimed to have conducted a "comprehensive review" of all NSAIDs, including sulindac, and their SJS/TEN risk in 2005, after receiving a citizen's petition from Bartlett's experts. Whether or not that review was truly comprehensive, it is pure speculation to assume that the FDA would have conducted a more thorough review in response to a citizen's petition from Mutual.

Moreover, Bartlett's argument that Mutual should have filed a citizen's petition with the FDA highlights yet another flaw with her negligence theory, which is that Mutual did not even need the FDA's permission to stop selling sulindac. It could have done so unilaterally at any time. The reason that Bartlett

has inserted the FDA as a middleman is that "almost all of the opinions which have addressed the issue have found that there is no common law duty to recall" products from the market, even if they are unreasonably dangerous. 5 Frumer & Friedman, supra, § 57.01[4], at 57-9. As this court noted in a previous order, "strict products liability requires . . . that manufacturers compensate consumers for the damage caused by unreasonably dangerous products, not necessarily that they remove such products from the market." Bartlett, 2010 DNH 131, at 21.

Bartlett has lengthened the chain of causation to include the FDA in an attempt to overcome the lack of any duty on Mutual's part to stop selling sulindac. Nevertheless, the duty problem persists. Bartlett has not presented any expert testimony or other evidence to suggest that a reasonable manufacturer in Mutual's position would have filed a citizen's petition advocating that its own drug be removed from the market, when it simply could have stopped selling the drug on its own. Bartlett argues that Mutual's conduct in filing nine citizen's petitions over the past decade establishes a "standard of care to file citizen's petitions." It is true that a defendant's internal practices can serve as evidence of a standard of care. See, e.g., Hood v. City of Nashua, 91 N.H. 98 (1940). But none of Mutual's citizen's petitions sought the removal of one of Mutual's own drugs, so they do not establish any standard of care

in that regard. Indeed, so far as the record indicates, there appears to be no precedent for such a petition.

As if the many problems discussed above were not enough, Bartlett's negligence theory also raises serious federal pre-emption concerns under the Supreme Court's decision in Buckman, 531 U.S. at 348, which held that "state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly pre-empted by" the Federal Food, Drug, & Cosmetic Act, 21 U.S.C. § 301 et seq. The claim in Buckman was that the defendant drug manufacturer "made fraudulent misrepresentations" to the FDA in the course of obtaining approval of a medical device, and "that such representations were at least a 'but for' cause of injuries that plaintiffs sustained. . . . Had the representations not been made, the FDA would not have approved the devices, and plaintiffs would not have been injured." Id. at 343.

The Supreme Court reasoned that such claims "inevitably conflict with the FDA's responsibility to police fraud consistently with [its own] judgment and objectives," and by raising the prospect of state tort liability for failure to communicate with the FDA, would give drug manufacturers "an incentive to submit a deluge of information that the [FDA] neither wants nor needs, resulting in additional burdens on the FDA's evaluation." Id. The Court concluded that "this sort of litigation would exert an extraneous pull on the scheme

established by Congress, and it is therefore pre-empted by that scheme." Id. at 353,

While this case involves an allegedly negligent nondisclosure to, rather than an intentional fraud on, the FDA, it raises some of the same concerns identified in Buckman. If drug manufacturers could be held liable under state law for negligent "failure to communicate with the FDA" (which is how Bartlett describes all of her negligence theories), then there is a very real possibility that the FDA would be "deluged" with citizen's petitions and other correspondence from manufacturers seeking to protect themselves against such state tort liability. That could impede the FDA's efforts to fulfill its regulatory mission in an efficient manner.

Whether Buckman's logic extends to this type of negligent nondisclosure claim is debatable. Some courts have construed Buckman narrowly as applying only to true "fraud-on-the-FDA" claims. See, e.g., Desiano v. Warner-Lambert & Co., 467 F.3d 85, 97 (2d Cir. 2006), aff'd without opinion by an equally divided court, 552 U.S. 440 (2008). Other courts, however, have read Buckman more broadly as encompassing other types of claims that raise similar concerns. See, e.g., Garcia v. Wyeth-Ayerst Labs., 385 F.3d 961 (6th Cir. 2004); Hughes v. Boston Sci. Corp., 669 F. Supp. 2d 701, 712 (S.D. Miss. 2009) (stating that the "Buckman holding did not turn on intentional versus negligent"

misrepresentation and calling that "a distinction without a difference"). This court need not choose a side in that debate, given the many other problems with Bartlett's negligence theory, as discussed above. Suffice it to say, however, that Mutual's argument for Buckman pre-emption is not a frivolous one.

In sum, Bartlett's claim that the FDA would have removed sulindac from the market in response to a citizen's petition or other submission from Mutual is largely counterfactual and otherwise based on improbable inferences and speculation. The claim therefore fails for lack of causation. The claim also runs into problems on the element of duty, especially to the extent that Bartlett is arguing that Mutual should have advocated that its own drug be removed from the market. Finally, while the court need not decide this issue in light of the lack of causation, the claim raises substantial federal pre-emption concerns under the Supreme Court's holding in Buckman, since it is premised on Mutual's alleged "failure to communicate with the FDA."

B. *Enhanced compensatory damages*

Since Bartlett has not presented sufficient evidence to support any of her negligence theories, this court must proceed to answer the other question briefed by the parties: whether

Bartlett can nevertheless recover enhanced compensatory damages on her strict liability claim. Under New Hampshire law, an award of compensatory damages may be enhanced in "exceptional cases" where the defendant's tortious "act is wanton, malicious, or oppressive." Stewart v. Bader, 154 N.H. 75, 87 (2006). An act is "wanton" if the defendant recklessly creates a risk of great harm. See Minion, Inc. v. Burdin, 929 F. Supp. 521, 525 (D.N.H. 1996) (McAuliffe, D.J.) (citing Thompson v. Forest, 136 N.H. 215, 220 (1992)). An act is "malicious" if the defendant has "ill will, hatred, hostility, or evil motive." Stewart, 154 N.H. at 87. An act is "oppressive" if it constitutes an abuse of power. See Walter L. Murphy & Daniel C. Pope, New Hampshire Civil Jury Instructions § 9.14, at 9-17 (1996). It is the plaintiff's burden "to present evidence of wanton, malicious or oppressive conduct." Figlioli v. R.J. Moreau Cos., 151 N.H. 618, 622 (2005).

In the summary judgment ruling, this court concluded that a reasonable jury could award enhanced compensatory damages in this case based on Mutual's "failure to survey the medical literature for information about sulindac's safety risks," and any other failures that followed from that one, such as a failure to report such information to the FDA. Bartlett, 2010 DNH 112, at 28. But that was before Bartlett submitted her evidence in support of that theory, and obviously before this court concluded that her

evidence was insufficient to prove that Mutual's failure to survey the medical literature caused her injuries. See Part III.A.iii, supra. The question is whether that lack of causation, which clearly defeats Bartlett's claim for regular compensatory damages based on that conduct, defeats her claim for enhanced compensatory damages as well.

Analogizing to punitive damages cases from other states, Bartlett argues that enhanced compensatory damages could nevertheless be awarded on her strict liability claim, which alleges that sulindac was a defective product unreasonably dangerous to consumers. It is true that, even though such claims focus on the product itself rather than the defendant's conduct, most courts allow punitive damages to be awarded where there is "proof that a higher level of fault exists than that which supports the actual damage award." 2 Frumer & Friedman, supra, 14.03[1][b], at 14-35 (quoting Racer v. Utterman, 629 S.W.2d 387, 396 (Mo. Ct. App. 1981)). In other words, most courts allow punitive damages where the defendant has acted recklessly in relation to the product, even if that reckless conduct was "immaterial" or legally unnecessary to a finding of strict liability. Id.

But punitive damages are prohibited by statute in New Hampshire, see N.H. Rev. Stat. § 507:16, and the New Hampshire Supreme Court has made clear that enhanced compensatory damages

are different from punitive damages. They are, "as their name indicates, compensatory and not punitive in nature." State v. Hynes, 159 N.H. 187, 198 (2009). They cannot "be awarded as a punishment to the defendant or as a warning and example to deter him and others from committing like offenses in the future." Stewart, 154 N.H. at 88. Nor can they be treated as somehow "separate from actual damages." Nollet v. Palmer, 2002 DNH 136, 7 (DiClerico, J.) (citing Vratsenes v. N.H. Auto. Inc., 112 N.H. 71, 73 (1972)). Rather, they must "reflect the aggravating circumstances of an injury caused to the plaintiff." DCPB, Inc. v. City of Lebanon, 957 F.2d 913, 915 (1st Cir. 1992) (applying New Hampshire law). So Bartlett's analogy to punitive damages is unpersuasive.

Both parties agree that there is no precedent in New Hampshire for awarding enhanced compensatory damages on a strict liability claim. This court need not decide whether such an award is ever possible. All that need be said is that such an award is not possible on the particular facts of this case. It would be inconsistent with New Hampshire law for enhanced compensatory damages to be awarded based on conduct by Mutual that, due to a lack of causation, could not serve as the basis for an award of regular compensatory damages (which is true of all of Mutual's conduct that arguably could be considered "wanton, malicious, or oppressive"). That would make the

enhanced compensatory damages "separate from actual damages" and would make them impermissibly punitive in nature. See Evans v. Taco Bell Corp., 2005 DNH 132, 35-36 (DiClerico, J.) ("Because [the plaintiff] has not shown a genuine issue of material fact as to whether [the defendant's] allegedly wrongful actions caused her claimed damages, she cannot recover enhanced compensatory damages.").[10]

IV. Conclusion

For the reasons set forth above, Mutual is granted judgment as a matter of law on Bartlett's claims for negligence and enhanced compensatory damages.

SO ORDERED.

Joseph N. Laplante
United States District Judge

Dated: September 14, 2010

cc: Keith M. Jensen, Esq.
Bryan Ballew, Esq.
Patrick J. O'Neal, Esq.

[10]Even without the ability to seek enhanced compensatory damages, Bartlett recovered $21.06 million in compensatory damages at trial, which consisted of $1.25 million in past medical expenses (stipulated by the parties), $2.377 million in future medical expenses, $933,000 in lost wages, and $16.5 million in pain and suffering.

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